# I. REMARKS

## Preliminary Remarks

Claims 148 to 151, 175, and 177 to 191 are pending, of which claims 148, 175, and 179 are independent. No claims are added, withdrawn, amended, or canceled. This response is accompanied by a declaration under 37 C.F.R. §1.132 by Dr. Badmaev.

The applicants respectfully request entry of this response and accompanying declaration pursuant to 37 C.F.R. §1.116, in that if the examiner maintains the claim rejections, this response places the claims in better form for appeal. This response is filed within the shortened statutory period for response, no fee due. The applicants respectfully request reconsideration and allowance of the present application.

## Patentability Remarks

*Rejection under 35 U.S.C. §112 –*

Claims 148 to 151, 175, and 177 to 191 were rejected under 35 U.S.C. §112, first paragraph, as containing subject matter not described in the specification. The applicants respectfully traverse.

Simply put, the examiner's argument appears to be that the "specification discloses a range of percentage for each boswellic acid" but provides "no disclosure and working examples for particular compositions comprising the boswellic acids herein with the particular amount." (emphasis in the original). The examiner cites *Vas-Cath v. Mahurkar*, 19 USPQ2d 1111 (CAFC 1991) and *In re Winkhaus*, 188 USPQ 129 (CCPA 1975) in support of her position and alleges that the amendments to the claims introduce new matter.

First, the specification as filed provides explicit support for the ranges of several claims. For example, support for the specific percentages and ranges of the compositions claimed in claims 179 to 181 can be found on page 18, lines 8 to 18. Certainly the examiner's rejection of these claims is improper. With respect to the remaining claims, the issue is whether the specification as filed provides sufficient

disclosure to one of ordinary skill in the art for the point percentages claimed. It is important to note that the specification as filed provides support for a composition comprising at least 5% by weight of β-boswellic acid, acetyl-β-boswellic acid, 11-keto-β-boswellic acid and acetyl-11-keto-β-boswellic acid (page 18, lines 1 to 8). This disclosure is sufficient to provide support for every point above 5%. The applicants draw the attention of the examiner to *In re Wertheim*, 191 USPQ 90 (CCPA 1976).

In *Wertheim*, the Court held that "(t)he primary consideration is *factual* and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure." *Wertheim*, 191 USPQ at 91 (emphasis in original). In *Wertheim*, the appellants had provided a description of the invention as employing solids content within the range of 25% to 60% along with specific embodiments of 36% and 50%. They were claiming a solids content ranging from between 35% and 60%. The Court found that on the basis of two specific examples, the appellants were entitled to a range of 35% to 60%.

In contrast, in the present application, the applicants have listed no fewer than 30 compositions describing various ranges and point percentages of compositions comprising four, three, and two boswellic acids (see, for example, pages 17 to 21). Similar to *Wertheim*, "(t)he PTO has done nothing more than to argue lack of literal support, which is not enough." *Wertheim*, 191 USPQ at 91. Clearly then the disclosure provides sufficient disclosure to one of ordinary skill in the art and claiming specific point percentages within these ranges is not "new matter". In other words, the rejection of the remaining claims is also improper.

The applicants now turn to the cases cited by the examiner in support of her rejection under 35 U.S.C. §112, first paragraph.

*Vas-Cath v. Mahurkar* deals with whether drawings in a prior design application provide sufficient written description under 35 U.S.C. §112, first paragraph, for the utility application under appeal, which the Court found they did. It is unclear what, if anything, this case has to do with the present application considering that the present application is not claiming priority to a design application. In addition, the applicants are not using any drawings in the present application nor the parent application for written description

purposes. If anything, this case furthers the applicants argument in the present application because it shows that the specification need not provide *ipsis verbis* support for claims.

*In re Winkhaus*, the appellant, faced with a rejection of the claims under 35 U.S.C. §132, admitted that the specification as filed did not disclose a specific feature but argued that sufficient disclosure could be found and would be obvious upon reading their specification. *Winkhaus*, 188 USPQ at 130. Unlike the appellants in *Winkhaus*, the present applicants do not admit that the specification as filed does not explicitly disclose specific percentages. Indeed, the applicants have argued and shown quite the opposite, namely that the specification not only provides specific support for almost all the point percentages, but also implicitly does so for the remainder in accordance with *Wertheim*. Even beyond that, it would be improper for the examiner to set forth any "new matter" rejection because *Wertheim* makes clear that the specification provides sufficient written description and enablement for all the claims currently pending.

In conclusion, it would appear that the examiner is misapplying the cases she has cited and has not contemplated the loose written description requirement of *Wertheim*. The applicants respectfully submit that the specification as filed fully supports claims 148 to 151, 175, and 177 to 191 per the requirements of 35 U.S.C. §112, first paragraph, and respectfully request withdrawal of this rejection.

*Rejections under 35 U.S.C. §103 –*

Claims 148 to 151, 175, and 177 to 191 were rejected under 35 U.S.C. §103(a) as being unpatentable over Nagasawa *et al.* (JP 04-288095) in view of Shao *et al.* (*Planta Med.* **64(4)**, 328 - 331, 1998). The applicants respectfully traverse.

Shao *et al.* is not available as a reference under 35 U.S.C. §102 and cannot therefore be used in a rejection under 35 U.S.C. §103. As the attached declaration under 37 C.F.R. §1.132 by Dr. Badmaev clearly states, he was a co-author of this scientific research publication, which describes his work, and he is the sole inventor of the subject matter described therein. The remaining co-authors, Y. Shao, C.T. Ho, C.K. Chin, W. Ma, and M.T. Huang were merely working under his direction. Therefore, Shao *et al.* is not an invention "by others" under 35 U.S.C. §102.

"Applicant's disclosure of his or her own work within the year before the application filing date cannot be used against him or her under 35 U.S.C. §102(a)." (M.P.E.P. §2131.01, emphasis added). The present application is a continuation of U.S. Pat. Appl. Ser. No. 09/302,510, filed April 30, 1999. Shao *et al.* was published in May 1998.

During prosecution of the parent application (U.S. Pat. Appl. Ser. No. 09/302,510), the examiner rejected the previously filed declaration by Drs. Majeed and Badmaev by stating that:

- "The declaration of Muhammed Majeed and Vladimir Badmaev lacks facts as documentary evidence, e.g., notebooks, photographs, or drawings to prove the conception derived from them alone, not from Shao, Ho, Chin, Ma, and Huang, especially Professor Chi-Tang Ho who is the major author for this cited reference."
- "Further, the statement in this declaration, 'the other authors of the literature reference Shao Y, Ho CT, Chin CK, Ma W, and Huang MT were contracted by us to perform experiments described in the report' is a totally unsupported statement."

These statements are very similar to those made by the examiner in *In re Katz*, 215 USPQ 14 (CCPA 1982). That examiner stated that "there is no evidence of record which makes it clear that appellant is the sole inventor of the claimed subject matter. Where a reference is from a collection of authors, it must be assumed that all authors contributed equally..." *Katz*, 215 USPQ at 16. Upon appeal, the Court reversed the claim rejections under 35 U.S.C. §102(a). The Court held that authorship of an article by itself does not raise a presumption of inventorship with respect to the subject matter disclosed and co-authors may not be presumed to be co-inventors merely from the fact of co-authorship. *Katz*, 215 USPQ at 18 (emphasis added). This is clearly what the current examiner has done when she states that Professor Chi-Tang Ho is, in her opinion, the major author for Shao *et al.* The examiner has provided no evidence that her allegation is true, in contrast to the applicants, who have already declared that none of the other co-authors of Shao *et al.* are inventors in the present application.

The Court also specifically addressed sufficiency of the declaration filed by Dr. David H. Katz and the requirement for additional evidence. In the declaration, the

appellant, Dr. Katz, explained that the co-authors of the publication were students working under the direction and supervision of the inventor. The Court concluded that the appellant's declaration was sufficient to overcome the rejection and that no additional evidence (*e.g.*, in the form of disclaiming affidavits or declarations) was required. *Katz*, 215 USPQ at 18. In other words, the law does not require any additional evidence, and in this case the examiner is clearly in error by dismissing the earlier declaration on the grounds that it does not contain documentary evidence.

Any remaining questions that the examiner may have about the earlier declaration, as well as the contributions of the co-authors in Shao *et al.* (besides Dr. Badmaev), are removed by the current declaration by Dr. Badmaev. This declaration reaffirms that Dr. Badmaev is a co-author of Shao *et al.* and that he is the sole inventor of the subject matter described therein, which is now claimed in the present application. The remaining co-authors, Y. Shao, C.T. Ho, C.K. Chin, W. Ma, and M.T. Huang, were merely working under the direction of Dr. Badmaev. Dr. Majeed is appropriately named as a co-inventor in the present application since the subject matter not coming from Shao *et al.* contains the contribution of Dr. Majeed.

The unavailability of Shao *et al.* leaves only Nagasawa *et al.* The applicants repeat their previous remarks with respect to Nagasawa *et al.*

The examiner alleged that Nagasawa *et al.* disclose that beta-boswellic acids such as β-boswellic acid, acetyl-β-boswellic acid, 11-keto-β-boswellic acid and acetyl-11-keto-β-boswellic acid are useful in treating autoimmune diseases. The examiner relied upon the English abstract of Nagasawa *et al.*, according to which the purpose of Nagasawa *et al.* was to provide a complement activity-inhibiting agent containing a specific β-boswellic acid derivative as an active ingredient, wherein the agent is effective for treating autoimmune diseases (emphasis added).

The English abstract, however, does not specifically state which compound or salt is the specific β-boswellic acid derivative used as the active ingredient of the agent. The English abstract does discloses that β-boswellic acid acetate was hydrolyzed to provide the objective compound (salt) of the formula shown. Hydrolysis of β-boswellic acid acetate removes the acetyl group. Therefore, Nagasawa *et al.* could not have

disclosed that *acetyl*-β-boswellic acid or *acetyl*-11-keto-β-boswellic acid is effective in treating autoimmune diseases. In contrast, all the pending claims comprise the administration of a composition containing at least one of acetyl-β-boswellic acid or acetyl-11-keto-β-boswellic acid.

Therefore, not only do Nagasawa *et al.* not provide any teaching or suggestion for one of ordinary skill in the art to modify their disclosure, they teach away from the use of acetyl-modified boswellic acids. In other words, the examiner is stretching the Nagasawa *et al.* abstract, which, if it teaches anything, teaches derivatization of acetyl-boswellic acids to remove the acetyl group, to cover an invention that claims a method using acetyl-modified boswellic acids. Clearly this rejection cannot and will not fit.

Furthermore, in making this rejection, the examiner has once again disregarded both the law, this time enunciated by the United States Supreme Court in *Graham v. John Deere Co.*, 148 USPQ 459 (1966), and U.S. Patent and Trademark Office procedures. The Manual of Patent Examining Procedure clearly instructs examiners "(w)hen applying 35 U.S.C. 103, the following tenets of patent law must be adhered to:

(A) The claimed invention must be considered as a whole;

(B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;

(C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and

(D) Reasonable expectation of success is the standard with which obviousness is determined." (M.P.E.P. §2141, emphasis added).

Considering the Nagasawa *et al.* abstract, *at best* it teaches using hydrolyzed, *i.e.*, non-acetyl boswellic acids. One of ordinary skill in the art reading the Nagasawa *et al.* abstract cannot reasonably expect that acetyl-containing boswellic acids would be successful, and the Nagasawa *et al.* abstract neither suggests desirability nor the obviousness of making such a modification.

Further in the same section, the M.P.E.P. adds, "(b)efore answering *Graham's* 'content' inquiry, it must be known whether a patent or publication is in the prior art under 35 U.S.C. §102. *Panduit Corp. v. Dennison Mfg. Co.*, 1 USPQ2d 1593, 1597"

(CAFC 1987, emphasis added). Since Shao *et al.* is not a reference available to the examiner, she should not have even considered using it, and in doing so has benefited from impermissible hindsight vision afforded by it and the claimed invention derived therefrom.

In conclusion, the applicants respectfully submit that claims 148 to 151, 175, and 177 to 191 are not unpatentable under 35 U.S.C. §103(a) over Nagasawa *et al.* in view of Shao *et al.* and respectfully request withdrawal of this rejection.

Claims 148 to 151, 175, and 177 to 191 were rejected under 35 U.S.C. §103(a) as being unpatentable over Taneja *et al.* (EP 0 755 940) in view of Shao *et al.* The applicants respectfully traverse.

As established above, Shao *et al.* is not available to the examiner under 35 U.S.C. §102 and cannot be used in rejecting claims under 35 U.S.C. §102 or §103. This leaves Taneja *et al.* as the only reference upon which the examiner can possibly reject claims 148 to 151, 175, and 177 to 191. The applicants repeat their previously filed arguments with respect to Taneja *et al.*

The examiner's rejection of the claims appears to be due to the disclosure in Taneja *et al.* that four boswellic acid compounds (acetyl-11-keto-β-boswellic acid, acetyl-β-boswellic acid, 11-keto-β-boswellic acid and β-boswellic acid) are effective in treating inflammation. The applicants have clearly shown using dictionary definitions that inflammation and autoimmune diseases are two different health disorders. To reiterate, "inflammation" is a pathologic process consisting of a dynamic complex of cellular and chemical reactions in response to an injury or abnormal stimulation caused by a physical, chemical, or biologic agent, while "autoimmune diseases" are diseases caused by cells or antibodies arising from and directed against an individual's own tissues. A substance effective in treating inflammation is not necessarily effective in treating autoimmune diseases. For example, aspirin is anti-inflammatory, but not effective in treating autoimmune diseases.

The examiner blithely asserted that "one of ordinary skill in the art would recognize that autoimmune diseases broadly encompass inflammatory diseases." Not only has the examiner not provided any evidence that one of ordinary skill in the art

would view autoimmune diseases as broadly encompassing inflammatory diseases but *if* one of ordinary skill in the art would place inflammatory diseases within the category of autoimmune diseases, a quick review of Stedman's Medical Dictionary would rectify this fallacy.

Therefore, the applicants respectfully submit that claims 148 to 151, 175, and 177 to 191 are not unpatentable under 35 U.S.C. §103(a) over Taneja *et al.* in view of Shao *et al.* and respectfully request withdrawal of this rejection.

## II. CONCLUSION

In view of the amendments and remarks above, the applicants respectfully submit that this application is in condition for allowance and request favorable action thereon.

In the event this response is not timely filed, the applicants hereby petition for an appropriate extension of time. The fee for this extension, along with any other additional fees which may be required with respect to this response, may be charged to Deposit Account No. 01-2300, referencing Attorney Docket No. 108064-00049.

Respectfully submitted,

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